

REMARKS

The Applicants thank the Examiner for the courteous telephone interview initiated by the Examiner on March 13, 2003. Present on the phone during the interview were Examiner Audet, Applicant's counsel Stephen Holmes, and co-applicant Dale DeVore.

During the interview, the Examiner requested clarification of certain protein (collagen) derivatizations. As explained by co-applicant Dale Devore, the specific derivatives were formed to make collagen more negatively charged and to attach pendant sulfhydryl groups. The former appears to provide better adhesiveness to tissue and the latter appears to improve cohesiveness of the tissue adhesive.

Applicant further thanks the Examiner for the short telephone interview on August 18, 2003 during which proposed amendments to the claims, and proposed responses to the Section 112 rejections were discussed. No agreement was reached. The Examiner will review further upon submission of the formal amendment.

In the Office Action, the Examiner indicated that claims 17-25 are withdrawn from consideration; rejected claims 1-16 under 35 U.S.C. § 112, first paragraph; rejected claims 1-16 under 35 U.S.C. § 112, second paragraph; rejected claims 1, 4-9, and 14-16 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,495,127 to Wallace et al.; rejected claims 1-10 and 14-16 under

35 U.S.C. § 102(b) as being anticipated 5,219,895 to Kelman et al.;<sup>1</sup> rejected claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Wallace et al. in view of Kelman et al. and U.S. Patent No. 6,161,544 to DeVore et al.; and rejected claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Wallace et al. in view of an article to Caroli et al. and further in view of U.S. Patent No. 5,767,152 to Nielson et al.

Applicants have amended claims 1, 3-10, 14 and 16; canceled claims 11-13, 15 and 17-25; and added new claims 26-35. Claims 1, 3-10, 14, 16 and 26-35 are pending in the present application.

At the outset, Applicants respectfully point out that previously withdrawn claims 17-25 have now been cancelled by this Amendment.

By way of background, Applicants' disclosure is directed toward, among other things, a novel tissue adhesive composition. Tissue adhesives or solders must have sufficient mechanical properties to strongly join tissues in surgical applications (see Applicants' specification at page 1, lines 8-9). Tissue adhesives should also be non-toxic (id., lines 10-14). In laser-assisted welding applications disclosed herein, tissues are joined together, the adhesive is applied, melted, and as it cools and solidifies, the tissues are bonded together.

Applicants' novel composition satisfies the above-described

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<sup>1</sup> Applicants respectfully note that the first two lines of page 14 of the Office Action indicate that claims 1-10 and 14-16 are rejected under 35 U.S.C. § 102(e) as being anticipated by Wallace et al. even though a Section 102 rejection based on this reference is previously articulated on page 13, and the text of the Office Action following the first two lines of page 14 refers to the Kelman et al. reference. Accordingly, Applicants assume the Examiner intended to reject claims 1-10 and 14-16 under 35 U.S.C. § 102(b) as being anticipated by Kelman et al.

requirements of tissue adhesives. The composition is collagen based, and is therefore non-toxic. Moreover, the high concentration of derivatized collagen is believed to provide a greater number of linkages so that upon exposure to laser light of a suitable wavelength, increased crosslinking with surrounding tissue is believed to occur (specification at page 3, lines 1-3; page 4, lines 3-6). Accordingly, a tissue adhesive having improved cohesive strength (Id.), and exceptional tensile strength of  $1000\text{g/cm}^2$ . (specification at page 14, lines 19-20) can be achieved. By attaching carboxyl groups and carboxyl/thiol groups through derivatization, it is believed that the net negative charge of the adhesive ionically interacts with the positively charged proteins in tissues so that the adhesive is soluble at physiologic pH (page 9, lines 8-11), and the adhesive will dissolve within the body over time.

Applicants realized, however, that derivatized collagen solutions saturate at about 10% or 100 mg/ml (see page 10, lines 13-14), far short of the concentration believed necessary to provide a sufficient number of cross-linking sites, as noted above. In light of the limited solubility of known derivatized collagen-based solutions, Applicants developed a unique process to make their novel tissue adhesive. As described in the specification, derivatized collagen was successively added to a derivatized collagen solution, and the solution was heated to 50 degrees Celsius, for example (page 10, lines 18-20). With each

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addition, the concentration is increased until a desired concentration is achieved (page 10, lines 21-22). Heating the solution is believed to cause the derivatized collagen to break down into smaller molecular weight units. Accordingly, as further discussed in the specification, a gelatinized and derivatized collagen is obtained (page 10, line 18 - page 11, line 3).

Gelatin, as generally understood, is obtained by heating collagen at relatively high temperatures in excess of its melting point for extended periods of time. In this process, gelatin is obtained by denaturing collagen. Prior art teachings of such gelatin, however, fail to teach or suggest high concentration (i.e., in the range of 300 mg/ml to 800 mg/ml ), gelatinized collagen, which is derivatized with a carboxyl group or with both carboxyl and thiol groups.

Moreover, as indicated in the Office Action dated November 19, 2003, Applicants previously amended claim 1, covering non-derivatized collagen was deemed to constitute a substantial change in subject matter from original claim 1 directed toward derivatized collagen. Thus, non-derivatized collagen material, such as gelatin, is distinguishable over derivatized collagen material.

Further, the Examiner maintains at pages 3, 4 and 6 of the Office Action dated August 22, 2003, that whether a particular derivatized collagen material, at a particular concentration, may be used as a tissue adhesive is unpredictable and requires undue

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experimentation (see Office Action of August 22, 2003 at pages 3, 4 and 6). Since such unpredictability should extend to compositions including gelatin, Applicants submit that their claimed tissue adhesive is novel and non-obvious over prior art teachings of gelatin for this reason as well.

Turning to the claims, claim 1 has been amended to reflect the above-described features of Applicants' novel composition. Namely, as amended, claim 1 recites a tissue adhesive, comprising collagen. The concentration of collagen in the adhesive being 300 mg/ml to 800 mg/ml. Support for the claimed range of concentrations may be found, for example, in the specification at page 3, lines 5-7. Amended claim 1 also recites that the collagen is derivatized with a COO<sup>-</sup> functional group. Support for this limitation can be found, for example, in the specification at page 10, lines 4-6. In addition, the collagen is gelatinized, support for which can be found, for example, in the specification at page 10, line 18 - page 11, line 3.

New claim 26 recites a tissue adhesive having a derivatized collagen concentration of 300 mg/ml to 800 mg/ml. The collagen is also gelatinized. These limitations are deemed to be adequately supported by Applicants' disclosure for reasons discussed above in regard to amended claim 1. In addition, new claim 26 requires that that the collagen is derivatized with carboxyl and thiol groups (see, for example, the specification at page 10, lines 4-6). New claims 27-35 depend either directly or indirectly from

new claim 26 and parallel claims 4-10, 14 and 16, respectively.

Turning to the rejections, Applicants respectfully traverse the Examiner's rejection of claims 1-16 under 35 U.S.C. § 112, first paragraph. Applicants respectfully submit that the Examiner's rejection with respect to claim 1 is moot in view of Applicants' amendment to claim 1 in which language related to derivatization further defines derivatization with a carboxyl group. As noted above, this feature is properly supported by Applicants' disclosure.

At pages 2-5 of the Office, the Examiner contends that the specification only supports claim language directed toward collagen derivatized with both carboxyl ( $\text{COO}^-$ ) and thiol ( $\text{SH}^-$ ) functional groups. In particular, the Examiner quotes page 9 of Applicants' specification describing enhancement of solder adhesive and cohesive characteristics by adding both carboxyl and thiol groups (see Office Action at page 4). The Examiner then concludes that the specification describes "throughout" such groups are "needed" for cohesive and adhesive strength, and suggests that in order to overcome the rejection, Applicants amend independent claim 1 to recite collagen derivatized with both carboxyl and thiol groups. Applicants respectfully disagree with the Examiner's characterization of their disclosure, and submit that such language in their broadest claims would unduly limit the scope of their invention.

The specification is not only directed toward formulations

having collagen derivatized with both carboxyl and thiol groups. Rather, derivatization with carboxyl groups without thiol groups is expressly described in the specification at page 10, lines 6-8 ("Solder formulations were prepared from chemically derivatized Type 1 collagen. Base compositions contained either COO<sup>-</sup> functional groups or both SH<sup>-</sup> (thiol) and COO<sup>-</sup> functional groups."; see also page 10, line 10: "Base preparations contained only COO<sup>-</sup> groups".) The specification thus provides support for collagen compositions including collagen derivatized with carboxyl groups, as well as carboxyl groups with thiol groups.

Moreover, Applicants respectfully submit that the portions of the specification discussed in the Office Action do not support the Examiner's conclusions. Those portions of the specification quoted in the Office Action describe a particular example of the invention in which collagen is derivatized with both carboxyl and thiol groups to enhance, i.e., improve, certain characteristics, namely adhesive and cohesive strength, of the resulting adhesive. Such disclosure, however, does not mean that with carboxyl derivatization alone, the resulting adhesive is somehow inoperable or unsuitable for its intended purpose. To the contrary, even without such dual derivatization, suitable adhesives can be obtained. (See page 11, lines 15-20.)

Amended claim 1, which recites collagen derivatized with a carboxyl group is thus supported by portions of the specification discussed above, as well as those cited in the Office Action.

Simply put, there is no language in the specification specifically limiting Applicants invention to collagen derivatized with both carboxyl and thiol groups. To the contrary, as noted above, the specification also provides support for carboxyl derivatization without thiol derivatization. Accordingly, incorporation of the suggested claim limitations (see page 4 of the Office Action) in Applicants' broadest claims, as suggested in the Office Action, would unduly limit the scope of the claims, and preclude Applicants from obtaining a scope of protection they are rightfully entitled to.

Although Applicants respectfully disagree with the Examiner's position that only collagen concentrations within a range of 300 mg/ml to 800 mg/ml are supported by the specification (see Office Action at pages 5-7), Applicants have amended claim 1 to further recite that collagen concentration being "at least equal to 300 mg/ml (30%) up to 800 mg/ml (80%)," in view of language proposed by the Examiner at page 7 of the Office Action.

Applicants also respectfully disagree with the arguments raised by the Examiner at pages 7-10 of the Office Action with respect to the cyanoacrylate-related limitation in claims 11-13. In order to advance prosecution of the present application, however, Applicants have cancelled claims 11-13, and submit that the Examiner's rejection is moot with respect to these claims.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 112, first

paragraph.

Applicants respectfully traverse the Examiner's rejection of claims 1-16 under 35 U.S.C. § 112, second paragraph. The Examiner alleges at page 10 of the Office Action that "[i]t is unclear whether Applicant is claiming a composition with derivatized collagen (an entire amount) or merely a concentration of derivatized collagen?" Applicants respectfully disagree with the Examiner's assertions. However, in an effort to expedite prosecution of the present application, Applicants have amended claim 1 to recite a tissue adhesive having a concentration of collagen "at least equal to 300 mg/ml (30%) up to 800 mg/ml (80%)", as suggested by the Examiner at page 7 of the August 22 Office Action. Claim 4 has also been amended to recite "up to 800 mg/ml." Applicants respectfully submit that the changes to claim 1 resolve any alleged ambiguity in the claims.

The Examiner further contends that claim 1 is indefinite because Applicants allegedly did not disclose in the specification "where the functional groups in question were to be attached within the collagen molecule." (See Office Action at page 11.) Applicants respectfully disagree.

The specification at page 10, lines 6-10 states:

Base compositions contained either COO<sup>-</sup> functional groups or both SH<sup>-</sup> (thiol) and COO<sup>-</sup> functional groups. The degree of derivatization with SH<sup>-</sup> functional groups was varied in attempts to modulate cohesive characteristics. Remaining free amine groups on the native collagen molecule were derivatized with COO<sup>-</sup> groups.

Emphasis added.

This cited portion of the specification expressly describes that derivatization occurs at the location of free amine groups on the native collagen molecule. Thus, the specification does indeed describe where carboxyl or thiol groups are attached during derivatization.

Further with respect to the Examiner's rejection under Section 112, second paragraph, Applicants have amended claim 5 to correct for antecedent basis. Moreover, Applicants respectfully submit that the Examiner's position in regard to carboxyl and thiol functional groups was addressed above with respect to the rejection under Section 112, first paragraph.

Applicants further respectfully submit that the Examiner's query as to whether the invention is a composition with both cohesive and adhesive strength or a composition with only cohesive or adhesive strength" (see Office Action at page 11) is misplaced.

Applicants respectfully submit that the claims are not limited to particular values of cohesive or adhesive strengths. Rather, Applicants' invention is defined by the claims, which as amended, recite among other features, a composition having a range of collagen concentrations, whereby the collagen is derivatized with a carboxyl group and is gelatinized. Applicants further respectfully submit that the assertions contained in the Office Action to the contrary are both legally and factually misplaced.

Turning to claims 8 and 11-13, Applicants submit that the Examiner's position is moot in light of Applicants' cancellation

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of claims 11-13.

Applicants also note that claim 2 has been cancelled in order to incorporate language related carboxyl derivatization into claim 1. In addition claims 3-10 have been amended to further define a tissue adhesive, and claim 10 has been amended to reflect the range of concentration of collagen fibrils, fibers or fiber bundles consistent with an aspect of the invention, as described in the specification at page 18, lines 3-5. Claim 15 has also been cancelled.

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 112, second paragraph.

Applicants respectfully traverse the Examiner's rejection of claims 1, 4-9 and 14-16 under 35 U.S.C. § 102(e) as being anticipated by Wallace et al. Applicants respectfully submit that the rejection is moot with respect to claims 2 and 15 in light of the cancellation of these claims. However, amended claim 1, for example, is not anticipated by Wallace et al. because the reference fails to teach each and every limitation of the claim. In particular, Wallace et al. at least fails to disclose the claimed tissue adhesive including collagen derivatized with a carboxyl group. Moreover, Wallace et al. does not disclose a concentration of gelatinized and carboxyl-derivatized collagen at least equal to 300 mg/ml up to 800 mg/ml.

As noted above, claim 1 has been amended to include subject

matter of claim 2 requiring collagen derivatization with a carboxyl group. Claim 2 was not rejected over Wallace et al., because one of the cited portions of the reference (col. 12, lines 56-57) reference fails to teach such derivatization.

Applicants note, however, that Wallace et al. fails to anticipate amended claim 1 for other reasons as well. Namely, the Examiner cites col. 27, line 10 of Wallace et al., and asserts that the reference teaches a "composition comprising derivatized collagen ... being at least equal to 300 mg or 400 mg to 800 mg". (Emphasis added) (See Office Action at page 13.) This portion of Wallace et al., however, describes mixing various materials with "400 mg of methylated collagen at 31 mg protein/ml." (Emphasis added.) It is unclear what "protein" Wallace et al. refers to. At best the protein is collagen, and its concentration is 31 mg/ml, much less than the claimed range of concentrations of 300 mg/ml to 800 mg/ml. Wallace et al., therefore, necessarily fails to teach the claimed composition having the specified range of collagen concentrations, as recited in amended claim 1.

Moreover, the cited portions of Wallace et al. teach derivatization of collagen, not gelatinized collagen, as recited in amended claim 1. The cited portions of Wallace et al. are silent as to any further heating of the collagen described therein, and Wallace et al. fails to teach gelatinization of the collagen described therein. As pointed out by the Examiner and discussed above, determining whether a particular derivatized

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collagen material can serve as a tissue adhesive requires undue experimentation. Accordingly, Applicants' claimed tissue adhesive including high concentration collagen, which is both derivatized with a carboxyl group and gelatinized is neither taught nor suggested by Wallace et al.

Accordingly, amended claim 1 is allowable over Wallace et al. and claims 4-9, 14 and 16 are allowable at least due to their dependence from amended claim 1.

Applicants respectfully traverse the Examiner's rejection of claims 1-10 and 14-16 under 35 U.S.C. § 102(b) as being anticipated by Kelman et al., and respectfully point out that this rejection is moot with respect to cancelled claims 2 and 15. The Examiner asserts that Kelman et al. teaches a collagen composition "with at least one of an acylating agent ... and sulfonating agent ... to derivatize collagen ... which could intrinsically yield 300-800 mg if derivatized to said degree". Applicants respectfully submit that in order for a reference to anticipate under Section 102, each and every claim limitation must be found in the reference. Whether an omitted teaching "could intrinsically" be present is not the test for anticipation. The Examiner has thus failed to establish anticipation based on Kelman et al. at least for this reason.

Moreover, even if Kelman et al. disclosed 300-800 mg of derivatized collagen, such teachings would be insufficient to anticipate claim 1, for example. As noted above, claim 1 recites

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a concentration of collagen in units of mg/ml, not just the weight of collagen present in a composition. Mere disclosure of the weight of collagen, by itself, does not indicate in any way the concentration of the collagen in terms of mass per unit volume, as required by amended claim 1.

Further, the cited portions of Kelman et al. are limited to disclosure of an amount of acylating agent to be mixed in a collagen solution (col. 5, line 1); performing acylation in an alkaline pH (col. 5, line 6); recovering a precipitate of reacted collagen containing substituent groups reacted with amine groups (col. 5, lines 28-30); and adjusting pH to 7.0 to 7.5 (col. 5, lines 38-40). None of the above teachings of Kelman et al. describe collagen concentration whatsoever, and thus necessarily fail to teach the claimed range of concentrations, as recited in amended claim 1.

In addition, Kelman et al. describes acylation of collagen, not gelatinized collagen. The cited portions fail to disclose any heating steps of the acylated collagen, which could achieve gelatinization, as recited in amended claim.

Claim 3 further recites derivatization with an SH<sup>-</sup> (thiol group), which the Examiner contends is disclosed by claim 17 of Kelman et al. reciting a sulfonating agent. As generally understood, sulfonation denotes a sulfonic group (SO<sub>3</sub><sup>-1</sup>), not an SH<sup>-</sup>, i.e., thiol, group. If anything, Kelman et al. teaches derivatization of collagen with a sulfonic group, not a thiol

group, as required by claim 3. Claim 3, therefore, is distinguishable over Kelman et al. at least for this reason as well.

In light of the above-described shortcomings of Kelman et al., Applicants respectfully submit that amended claim 1 is allowable over the applied reference, and claims 3-10, 14 and 16 are allowable at least due to their dependence from amended claim 1.

Applicants respectfully traverse the Examiner's rejection of claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Wallace et al. in view of Kelman et al. and DeVore et al. Amended claim 1, for example, is not obvious over any of the applied references, because neither one, taken alone or in combination, teaches each and every element of the claim. In particular, none of the applied references teaches the claimed tissue adhesive including collagen that is both carboxyl-derivatized and gelatinized, and in a concentration in a range of 300 mg/ml to 800 mg/ml.

As noted above, neither Wallace et al. nor Kelman et al. teach the claimed tissue adhesive because, among other reasons, neither teaches the claimed concentration of carboxyl-derivatized and gelatinized collagen. Applicants note that their claimed concentration cannot be obtained through routine experimentation and would not have been obvious to one of ordinary skill, particularly in light of the teachings of Wallace et al. and

Kelman et al. As noted above, and discussed in Applicants' specification (see page 10, lines 13-22) since collagen typically becomes saturated at less than 10%, a new technique was developed to obtain carboxyl-derivatized collagen with the claimed concentration of 300 mg/ml to 800 mg/ml. None of the cited references even recognize that collagen solutions saturate at relatively low concentrations. Accordingly, given the difficulties associated with achieving the claimed concentration, and, moreover, since Wallace et al. and Kelman et al. are entirely silent with respect to the claimed concentrations, Applicants respectfully submit that their claimed tissue adhesive, as recited in amended claim 1, would not have been obvious to one of ordinary skill.

With respect to Devore et al., the Examiner asserts, apparently in reference to claim 3, that the reference teaches "4-Mercapto-1,8,Napthalic Anhydride [hereinafter "4-Mercapto"] (as Applicant used), to yield the SH- functional group." (Office Action at page 15.) In addition, the Examiner asserts that "it was known that SH- provides cohesive strength ... of a collagen-based tissue adhesive." Id. Applicants respectfully disagree with the Examiner on both counts.

Devore et al. lists 4-Mercapto, along with many other compounds, but the use of 4-Mercapto in the reference is entirely different than that of 4-Mercapto in Applicants' specification. Specifically, Devore et al. discloses 4-Mercapto as a

"destabilizing agent" (col. 5, lines 32-35) for softening eye tissue ("In the methods to be described herein, chemical agents which soften, degrade or 'destabilize' the structural components of the stroma are topically administered to the cornea 10." Col. 4, line 66-Col. 5, line 2. Thus, Devore et al. teaches application of 4-Mercapto to tissue itself for the purpose of degrading or destabilizing the tissue. Such use is unrelated to derivatization of collagen of an adhesive for the purpose of gluing tissues. Accordingly, Devore et al. teaches away from Applicants claimed tissue adhesive.

Applicants further disagree with the Examiner's assertion that it is known that thiol-derivatized collagen has beneficial tissue adhesive properties. The Office Action fails to cite any prior art in support of the contention that SH- derivatized collagen provides improved cohesive strength, but only states that such was "known". Applicants respectfully submit that the Examiner's assertion, without citation to corroborative prior art, does not evidence motivation to combine the applied references in the manner proposed in the Office Action.

In any event, even if Devore et al. disclosed all that the Office Action alleges (see page 15), the reference would still fail to overcome the above described shortcomings of both Wallace et al. and Kelman et al. Accordingly, Applicants respectfully submit that amended claim 1 is allowable over the Examiner proposed combination of Wallace et al., Kelman et al. and Devore

et al., and claims 3-10, 14 and 16 are allowable at least due to their dependence from amended claim 1. As noted above, claims 2 and 15 have been cancelled, and therefore the Examiner's rejection is moot with respect to these claims.

Applicants respectfully traverse the Examiner's rejection of claims 1-16 under 35 U.S.C. the Examiner's rejection of claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Wallace et al. in view of Caroli et al. and Nielson et al. Although the Examiner has rejected each of claims 1-16 as being unpatentable over Wallace et al. in view of Caroli et al. and Nielson et al., the text of this rejection focuses on claims 11-13 and the Examiner relies on Caroli et al. and Nielson et al. allegedly for providing teachings of cyanoacrylates. Applicants respectfully submit, however, that the Examiner's rejection is moot with respect to cancelled claims 11-13. Moreover, the above-described deficiencies of Wallace et al. cannot be overcome by the cyanoacrylate teachings of Caroli et al. and Nielson et al. Accordingly, Applicants respectfully submit that amended independent claim 1 is allowable over the Examiner's proposed combination of Wallace et al., Caroli et al. and Nielson et al. In addition, claims 3-10, 14 and 16 are allowable at least due to their dependence from amended independent claim 1.

Turning to new claims 26-35, new independent claims 26 is similar to amended claim 1, but further recites derivatization with a thiol group, as also required by claim 3. Accordingly,

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new claim 26 is deemed allowable at least for reasons discussed above in regard to claims 1 and 3. Moreover, new claims 27-35 parallel claims 4-10, 14 and 16, respectively. Claims 27-35 are therefore deemed allowable at least due to their dependence from claim 26, and for reasons discussed above in connection with claims 4-10, 14 and 16.

Since Applicants have retained claim language related to derivatized collagen, Applicants submit that the independent claims present in this application are not directed toward "substantially change[d] subject matter" (see Office Action dated November 19, 2003), to the extent this phrase is understood. Thus, in light of the foregoing amendment and remarks, Applicants respectfully request entry of this Amendment, reconsideration and withdrawal of the outstanding rejections and objections, and a timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 020900.

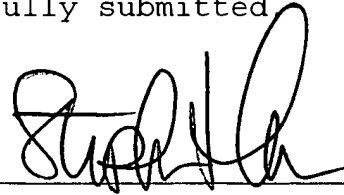
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If a fee is required for an extension of time under 37 C.F.R.  
§ 1.136 not accounted for above, such an extension is requested  
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Respectfully submitted

By: \_\_\_\_\_

A handwritten signature in black ink, appearing to read 'Stephen Holmes', written over a horizontal line.

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